

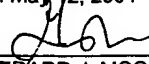
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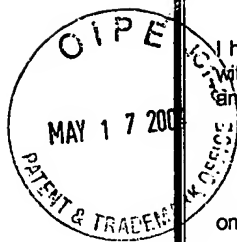
"Assistant Commissioner for Patents  
Washington, D.C. 20231"

on May 12, 2004

  
GERARD J. MCGOWAN, JR.  
Reg. No. 29,412  
Attorney for Applicant(s)

05/12/04  
Date of  
Signature

**PATENT**  
#02-0496-UNI  
Case #F7663(V)



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Diks et al.  
Serial No.: 10/626,451  
Filed: July 24, 2003  
For: COMPOUNDS AND THEIR USE IN FOOD COMPOSITIONS

Edgewater, New Jersey 07020  
May 12, 2004

**SUBMISSION OF PRIORITY DOCUMENT**

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

Pursuant to rule 55(b) of the Rules of Practice in Patent Cases, Applicant(s) is/are submitting herewith a certified copy of the European Application No. 02255241.8 filed July 26, 2002, upon which the claim for priority under 35 U.S.C. § 119 was made in the United States.

It is respectfully requested that the priority document be made part of the file history.

Respectfully submitted,



Gerard J. McGowan, Jr.  
Reg. No. 29,412  
Attorney for Applicant(s)

GJM/mt  
(201) 840-2297

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**Attestation**

Die angehefteten Unterlagen stimmen mit der ursprünglich eingereichten Fassung der auf dem nächsten Blatt bezeichneten europäischen Patentanmeldung überein.

The attached documents are exact copies of the European patent application described on the following page, as originally filed.

Les documents fixés à cette attestation sont conformes à la version initialement déposée de la demande de brevet européen spécifiée à la page suivante.

**Patentanmeldung Nr.    Patent application No.    Demande de brevet n°**

02255241.8

Der Präsident des Europäischen Patentamts;  
Im Auftrag

For the President of the European Patent Office

Le Président de l'Office européen des brevets  
p.o.

**R C van Dijk**

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Anmeldung Nr:  
Application no.: 02255241.8  
Demande no:

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Anmelder/Applicant(s)/Demandeur(s):

UNILEVER PLC  
Unilever House  
Blackfriars  
P.O. Box 68  
London EC4P 4BQ  
GRANDE BRETAGNE

Bezeichnung der Erfindung/Title of the invention/Titre de l'invention:  
(Falls die Bezeichnung der Erfindung nicht angegeben ist, siehe Beschreibung.  
If no title is shown please refer to the description.  
Si aucun titre n'est indiqué se référer à la description.)

Compounds and their use in food compositions

In Anspruch genommene Priorität(en) / Priority(ies) claimed /Priorité(s)  
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## COMPOUNDS AND THEIR USE IN FOOD COMPOSITIONS

### Field of the Invention

The present invention relates to plant derived compounds and analogues and  
5 derivatives thereof and their use in food compositions.

### Background to the Invention

Various plant sterols and plant sterol derived compounds have (when  
consumed in the right form) a known and well-documented effect on blood  
cholesterol level. Among these are compounds like  $\beta$ -sitosterol, the  
10 hydrogenated form thereof ( $\beta$ -sitostanol), as well as esterified forms thereof.  
Sterols have been reported to be capable of lowering the level of blood  
cholesterol (Pollak & Kritchevsky, Monographs in Atherosclerosis, 1981). In  
particular, the group of 4-desmethylsterols, 4-monomethylsterols, their  
hydrogenated forms and fatty acid esters have been reported to have a  
15 beneficial effect on blood cholesterol level, in particular on LDL-cholesterol.

We have now found that compounds of the above type when used as  
additives in bulk dairy and non-dairy food products also enhance consumer  
perception of creaminess in the products.

20

WO-A-99/44442 discloses a manufacturing process for food products  
whereby a homogeneous emulsifier-free suspension of at least one  
hydrophobic and/or high melting point substance in an aqueous medium and  
a thickener can be prepared. The hydrophobic substance may be chosen  
25 from phytosterols, phytostanols and their esterified derivatives. The process

is said to be particularly suited to manufacture of milk and milk derivative food compositions.

### **Definition of the Invention**

5 In a first aspect, the present invention provides a food composition comprising a dairy product or a derivative or analogue thereof, an emulsifier and a creaminess enhancer selected from phytosterols, phytostanols, synthetic analogues thereof and their esterified derivatives.

10 In a second aspect, the present invention provides use of at least one compound selected from phytosterols, phytostanols, synthetic analogues thereof and their esterified derivatives as a creaminess enhancer in a food comprising a dairy product or a derivative or analogue thereof.

### **Detailed Description of the Invention**

15 Food compositions according to the present invention and those resulting from use according to the present invention have been found to exhibit enhanced creaminess. Creaminess *per se* is a well known property of dairy type products however, the present invention seeks to enhance the  
20 creaminess of those products which already have a substantial creamy property and to add to or boost creaminess in those which have little or no creaminess. Without being bound by any theory or explanation, the applicants have conjectured that the creamy impression given by *inter alia*, full fat dairy products such as full fat milk, cream and dairy ice cream is at least  
25 partly due to the presence of milk fat globules comprising a butterfat and protein complex structure. It is therefore surprising that this perception can be endowed or enhanced by creaminess enhancers as herein defined.



The Dairy Product, Derivative or Analogue

As used herein, the term dairy product means a product consisting of, or adapted only slightly from, the naturally occurring source (e.g. milk, skimmed milk etc.). Reference to a dairy product derivative means a processed dairy product such as yoghurt. A dairy product analogue is one where all or a major part of the naturally occurring animal product is replaced by a vegetable fat or non-fat animal product such as protein, or synthetic substitute of any of these, and mixtures thereof.

10

The dairy product may for example be milk or milk with a reduced fat content such as skimmed milk or semi-skimmed milk. As used herein, the term "milk" refers to cow's milk, sheep milk, goat milk or the like and derivatives thereof should be construed likewise.

15

Other dairy products or dairy product derivatives or analogues suitable for use in the present invention include yoghurt, yoghurt drinks, yoghurt ice creams, creams (such as whipping cream, cooking cream, spoonable creams, pourable cream, coffee creamer); cream cheese, fresh cheese, creme fraiche, Kefir, Umer, quark, soured milk (karne milk), fromage frais, fromage blanc, cottage cheese, buttermilk and whey and products made from buttermilk or whey.

20

The product may also be any of the foregoing, wherein the dairy fat content is partly or wholly replaced by vegetable fat.

25

The primary product will constitute all of the final composition other than the creaminess enhancer, emulsifier (where applicable) and optional other ingredients, for example as described further hereinbelow. Typically, it will comprise from 40% to 99.99%, preferably from 70% to 99.5%, more preferably from 50% to 95% by weight of the total composition.

30

Preferred primary products have a fat content of from 0.2% to 10%, more preferably from 0.5% to 2% by weight.

#### The Emulsifying Agent

5

The emulsifying agent is an essential feature of the first aspect of the invention and an optional feature of the second aspect of the present invention.

10

One or more emulsifying agents may be used. These may be selected from a wide range of emulsifiers well known in the art for use in dairy or dairy-like products. A non-exhaustive list comprises fatty acid mono- or diglycerides and their corresponding esters, lecithin, citric acid ester, lactic acid ester, polyoxysorbitan monoester, tartaric acid ester and mixtures thereof.

15

Some specific usable emulsifying agents are those designated E470, E471, E472, E473, E474, E475, E476 and E477.

The total amount of emulsifying agent is preferably from 0.0001% to 2%, more preferably from 0.001% to 0.5%, still more preferably from 0.01% to 0.3% by weight of the food composition.

20

#### The Creaminess Enhancer

25

The creaminess enhancer is selected from one or more of phytosterols, phytostanols, synthetic analogues of phytosterols and phytostanols and esterified derivatives of any of the foregoing.

30

The total amount of creaminess enhancer is typically incorporated in an amount of from 0.1% to 20%, preferably from 0.3% to 15%, more preferably

from 0.5% to 8%, still more preferably from 0.5% to 2% by weight of the food composition.

Phytosterols, also known as plant sterols or vegetable sterols can be  
5 classified in three groups, 4-desmethylsterols, 4-monomethylsterols and  
4,4'-dimethylsterols. In oils they mainly exists as free sterols and sterol esters  
of fatty acids although sterol glucosides and acylated sterol glucosides are  
also present. There are three major phytosterols namely beta-sitosterol,  
stigmasterol and campesterol. Schematic drawings of the components meant  
10 are as given in "Influence of Processing on Sterols of Edible Vegetable Oils",  
S.P. Kochhar; Prog. Lipid Res. 22: pp. 161-188.

The phytostanols are the respective 5 $\alpha$ - saturated derivatives of phytosterols  
such as sitostanol, campestanol and ergostanol and their derivatives.  
15

Preferably the phytosterol or phytostanol is selected from the group  
comprising fatty acid ester of  $\beta$ -sitosterol,  $\beta$ -sitostanol, campesterol,  
campestanol, stigmasterol, stigmastanol and mixtures thereof.

20 The most preferred creaminess enhancer is a fatty acid ester of  $\beta$ -sitosterol or  
 $\beta$ -sitostanol.

#### Fatty Acid Esters

25 The phytosterols according to the invention are preferably esterified with a  
fatty acid. Preferably the sterols are esterified with one or more C<sub>2-22</sub> fatty  
acids. For the purpose of the invention the term C<sub>2-22</sub> fatty acid refers to any  
molecule comprising a C<sub>2-22</sub> main chain and at least one acid group. Although  
not preferred within the present context the C<sub>2-22</sub> main chain may be partially  
30 substituted or side chains may be present. Preferably, however the C<sub>2-22</sub> fatty  
acids are linear molecules comprising one or two acid group(s) as end

group(s). Most preferred are linear C<sub>8-22</sub> fatty acids as occur in natural oils.

Suitable examples of any such fatty acids are acetic acid, propionic acid, butyric acid, caproic acid, caprylic acid, capric acid. Other suitable acids are  
5 for example citric acid, lactic acid, oxalic acid and maleic acid. Most preferred are lauric acid, palmitic acid, stearic acid, arachidic acid, behenic acid, oleic acid, cetoleic acid, erucic acid, elaidic acid, linoleic acid and linolenic acid.

10 When desired a mixture of fatty acids may be used for esterification of the sterols. For example, it is possible to use a naturally occurring fat or oil as a source of the fatty acid and to carry out the esterification via an interesterification reaction. Use of a natural source nearly always results in a mixture of fatty acids.

15 In a particular embodiment, the fatty acid mixture contains a high amount (>50%, preferably >70%, further preferred >80%) of unsaturates, whether monounsaturated fatty acids (MUFA) and/or polyunsaturated fatty acids (PUFA). This does not only provide the advantage of e.g. PUFA itself having  
20 good blood cholesterol lowering capacity, but also of the sterols esters prepared with such fatty acids being considered as having a higher solubility and blood cholesterol lowering efficacy in the body.

Preferably fatty acid mixtures of sunflower, safflower, rapeseed, linseed, linola and/or soybean are used. These are typical sources of high PUFA and/or low  
25 SAFA. Suitable esterification conditions are for example described in WO 92/19640.

### Thickeners

Preferably, the food composition comprises a thickener, for example selected from xanthan gum, locust bean gum, carrageenan, pectin, guar gum, a starch  
5 and mixtures thereof.

Preferably the amount of thickener from 0.01% to 5%, more preferably from 0.1% to 2% by weight of the total food composition.

### 10 Other Optional Ingredients

The total food composition may contain one or more other optional ingredients. These may be incorporated in the primary product or in the final composition or added to any premix or in any processing stage.

15

The optional ingredients may for example be chosen from stabilisers, antioxidants and other preservatives, colours, flavourings, fruit concentrates, vitamins, supplements and mixtures thereof. Suitable fruit concentrates  
include those derived from apricot, strawberry, cherry and any combination  
20 thereof.

### Processing

The creaminess enhancing agent and emulsifier (where appropriate) may be  
25 incorporated by simple admixture with the other ingredients of the final product. Alternatively they may be pre-mixed with a proportion of the total product or pre-mixed with some or all of one or more other components of the final product, or with a precursor component or components (e.g. milk in the case of yoghurt). The premix will then be admixed into the total product bulk.

30

The present invention will now be described by way of the following non-limiting examples.

### Examples

5

In these examples, all percentages are by weight of the composition. "Sterol Ester" means ester of sunflower oil fatty acid and  $\beta$  sitosterol.

#### Example I – Milk

10

1. Formulation:

95.955% liquid skimmed milk

3.33% dairy double cream (48% fat)

0.015% xanthan gum

15

0.7% sterol ester

overall:

dairy fat = 1.6%

other fat = 0.3%

TOTAL fat = 1.9%

20

2. Processing:

The milk is UHT processed and aseptically packed. The UHT process is effected using direct steam injection using heat exchangers.

25

The process utilises the following steps:

- preparation of premix (where sterol ester is added)
- preheat to about 80°C
- direct UHT to 148°C for 3 seconds
- flash vessel
- 30 - cool to about 80°C
- homogenise at 150 bar and then 50 bar

- cool further to below 20°C
- pack aseptically

### Example II – Yoghurt

5

#### 1. Formulation:

	Description	Quantity %
	<b>Skimmed yoghurt base</b>	<b>80.0000</b>
10	Skimmed milk	72.8792
	Milk caseinate	1.1200
	Whey protein	0.8000
	Skimmed milk powder	1.6000
	Sterol ester	1.1000
15	Mono and di-glycerides	0.0008
	Streptococcus thermophilus	present
	Lactobacillus bulgaricus	present
	Bifidobacterium	present
	Sugar	2.5000
20	<b>Strawberry fruit preparation</b>	<b>20.0000</b>
	Strawberry pieces	6.7000
	Water	5.2720
	Fructose containing syrup	3.4200
	Sugar	3.1000
25	Modified starch: acetylated distarch adipate (E1422)	0.7800
	Strawberry juice concentrate	0.4800
30	Stabilizers: pectin (E440) and Xanthan gum (E415)	0.1000
	Colouring: Fruit- and plant extract	0.0800

Acidifier: citric acid (E330) 0.0400

Natural flavouring 0.0280

5

2. Processing:

- Add all "yoghurt base" ingredients to the milk
- 10 - Pre-treatment of milk-mixture prior to addition of cultures (homogenisation, pasteurisation)
- add cultures
- 15 - incubation until pH 4.5 at temperature of 43°C
- cool to about 10°C
- add flavouring/fruit preparation (aseptically)
- 20 - pack
- transfer to cold store at about 4°C.

25

Example III Skimmed Milk

Formulation:

30 0.015% carrageenan  
0.7% sterol ester  
balance skimmed milk

Process : as Example I

35

The products prepared according to Examples I, II and III were tested on a consumer panel test against corresponding controls lacking the sterol ester. The panel reported an enhanced perception of creaminess in the Examples of the invention over their respective controls.



**CLAIMS**

1. A food composition comprising a dairy product or derivative or analogue thereof, an emulsifier and a creaminess enhancer selected from phytosterols, phytostanols, synthetic analogues thereof and their esterified derivatives.  
5
2. A composition according to claim 1, wherein the dairy product or its analogue or derivative comprises milk, milk of reduced fat content, yoghurt, yoghurt drinks, yoghurt ice creams, creams (such as whipping cream, cooking  
10 cream, spoonable creams, pourable cream, coffee creamer); cream cheese, fresh cheese, creme fraiche, Kefir, Umer, quark, soured milk (karne milk), fromage frais, fromage blanc, cottage cheese, buttermilk and whey and products made from buttermilk or whey.
- 15 3. A composition according to either preceding claim, comprising from 0.1% to 20%, preferably from 0.3% to 15%, more preferably from 0.5 to 8%, most preferably from 0.5% to 2% by weight of the total composition of the creaminess enhancer.
- 20 4. A composition according to any preceding claim, comprising from 0.001 to 0.5%, preferably from 0.01% to 0.3% by weight of the total composition of the emulsifier.
- 25 5. Use of at least one compound selected from phytosterols, phytostanols, synthetic analogues thereof and their esterified derivatives as a creaminess enhancer in a food composition comprising a dairy product or derivative or analogue thereof.

6. Use according to claim 5, wherein the dairy product or its analogue or derivative comprises milk, milk of reduced fat content, yoghurt, yoghurt drinks, yoghurt ice creams, creams (such as whipping cream, cooking cream, spoonable creams, pourable cream, coffee creamer); cream cheese, fresh  
5 cheese, creme fraiche, Kefir, Umer, quark, soured milk (karne milk), fromage frais, fromage blanc, cottage cheese, buttermilk and whey and products made from buttermilk or whey.
7. Use according to claim 5 or claim 6, comprising from 0.1% to 20%,  
10 preferably from 0.3% to 15%, more preferably from 0.5 to 8%, most preferably from 0.5% to 2% by weight of the total composition of the creaminess enhancer.
8. Use according to any of claims 5-7, wherein the food composition  
15 further comprises an emulsifier.
9. Use according to claim 8, comprising from 0.001 to 0.5%, preferably from 0.01% to 0.3% by weight of the total composition of the emulsifier.

ABSTRACTCOMPOUNDS AND THEIR USE IN FOOD COMPOSITIONS

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Use of at least one compound selected from phytosterols, phytostanols, synthetic analogues thereof and their esterified derivatives as a creaminess enhancer in a food composition comprising a dairy product or derivative or analogue thereof.

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